DEC 2 1 2012

510(k) Summary

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c. Date prepared

March 28, 2012

d. Name of device

Trade Name:	PREXION 3D
Common Name:	Computed tomography x-ray system
Classification Name:	X-ray, tomography, computed, dental
Classification Regulation:	21 CFR 892.1750

e. Predicate devices

The PREXION 3D is substantially equivalent to the following legally marketed device:

510(k) Number	Trade name	Product code
K063622	FINECUBE	OAS
K103659	CS 9300	OAS

The predicate devices are hereinafter called "the FINECUBE (k063622)" or "CS 9300 (k103659)" in this application.

f. Description of the device

The PREXION 3D consists of scanner and two software including Console software, and Viewer software used for the Image Analysis System and Data processing. A qualified computer named Console computer is distributed with the PREXION 3D.

The PREXION 3D uses the Image Analysis System and the processed data acquired by the scanner to analyze 2D and 3D images, perform image edition, such as creating cross-section views, and output results to a printer or other output device.

During scanning, X-rays are generated from the X-ray tube head mounted in the arm of the scanner and the X-rays passing through a patient are then detected by the flat panel detector of the scanner under the control of the firmware and the Console software installed on the qualified computer. The detected X-ray absorption data is processed by the Console software and viewer software on a computer to reconstruct images. Scanning is performed using X-ray penetration signals of a patient taken from multiple directions for the diagnosis of hard tissue including bones and teeth of the jaw and mouth cavity. The PREXION 3D performs two types of scanning including CT scan generating two (2) and three (3) dimensional images and Panoramic scan generating two (2) dimensional images.

g. Indications for Use

The PREXION 3D is intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillo-facial region at the direction of healthcare professionals as diagnostic support.

h. Statement of substantial equivalence

The PREXION 3D was developed from the FINECUBE (k063622) by adding panoramic scan function. Accordingly, the characteristics of the PREXION 3D are identical or similar to those of the FINECUBE (k063622) regarding X-ray Generation Device characteristics including tube voltage, tube current, and Focal Spot Size, X-ray image capturing device including type of detector, Pixel size, pixel number. (See Table 6-1 Comparison Table).

The only difference of the PREXION 3D from the FINECUBE (k063622) is addition of panoramic scanning function. The panoramic scanning function of the PREXION 3D is similar to CS 9300 (k103659). Both the PREXION 3D and CS 9300 (k103659) have the panoramic scanning function in addition to CT scan function. The PREXION 3D has the similar characteristics regarding intended use, X-ray Generation Device characteristics

including tube voltage, tube current, and Focal Spot Size, X-ray image capturing device including type of detector, pixel number as CS 9300 (k103659).
By considering above device characteristics, the intended use of the PREXION 3D is identical to part of intended use of the CS 9300 (k103659), and similar to the intended use of the FINECUBE (k063622).

In order to ensure same performance characteristics as predicate devices, software verification/validation, performance testing, and risk analysis were performed. Such test results and risk analysis indicate that the PREXION 3D meets the requirements of the recognized consensus or voluntary standard. Based on the information presented above we conclude that the PREXION 3D is substantially equivalent to the predicate devices and does not raise any new questions regarding safety or effectiveness.

i. Comparison table

Table 6-1 compares the characteristics between the PREXION 3D and the predicates.

Table 6-1. Comparison Table

		PREXION 3D	FINECUBE (k063622)	CS 9300 (k103659)
Indications for Use		PREXION 3D is intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillo-facial region at the direction of healthcare professionals as diagnostic support.	FINECUBE is an x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists.	The CS 9300 and CS 9300C are systems intended to produce two-dimensional and three-dimensional digital x-ray images of the dento-maxillo-facial, and ENT (Ear, Nose and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients. In addition, the CS 9300C is intended to produce cephalometric images. This includes imaging the hand and. wrist to obtain the carpus image for growth and maturity assessment.
X ray Generation Device	Tube Voltage	90kV	90kV	60 - 90kV
	Tube Current	4mA	4mA	2 - 15mA
	Focal Spot Size	0.2mm	0.2mm	0.7mm
X ray image capturing device	Detector	FPD	FPD	FPD (TFT)
	Pixel size	200μm (CT) 100μm (Panoramic)	200μm	-
	Pixel number	616 x 608 (CT) 1216 x 72 (Panoramic)	608 x 616	64 x 1536 pixels (Panoramic)
	Size of Area receiving X-ray.	123.2mm x 121.6mm (CT) 10mm x 131.6mm (Panoramic)	121.6mm x 123.2mm	5 x 149 mm max (Panoramic)
	Number of Bit	14bits	12bits	14 bits

		PREXION 3D	FINECUBE (k063622)	CS 9300 (k103659)
Scanner	SID/SOD	700mm/468mm (Hi-Def/Ultra Hi-Def/Rapid Scan) 700mm/322mm (Hi-Res)	700mm/322mm(Magnification imaging) 700mm/468mm(Wide area imaging)	615mm (SID)
	Dimension (W×D×H)	1170mm×1530mm×1930mm	1170mm×1530mm×1930mm	1158mm×1595mm×2378mm
	Weight	390kg	390kg	160kg
Scan mode		CT Scan and Panoramic Scan	CT Scan	CT Scan and Panoramic Scan
Panoramic scan Performance	Scan time	16.2 sec	-	4 - 16 sec
CT scan Performance	Scan time	8.6 sec (Rapid Scan) 16.8 sec (Hi-Def/Hi-Res) 33.5 sec (Ultra Hi-Def/Ultra Hi-Res)	19sec. (Standard mode) 37sec. (High density mode)	12 - 20 sec 28 sec
	FOV (voxel size)	φ81mm/H74mm (Hi-Def/Ultra Hi-Def/Rapid Scan)	Wide area imaging φ82.0mm H75.1mm	φ170mm/H135mm (0.090mm - 0.500mm)
		φ56mm/H51mm (Hi-Res/Ultra Hi-Res)	Magnification imaging φ56.5mm, H51.7mm	φ170mm/H110mm (0.090mm - 0.500mm)
		-	-	φ170mm/H60mm (0.090mm - 0.500mm)
		-	-	φ100mm/H100mm (0.090mm - 0.500mm)
		-	-	φ80mm/H80mm (0.090mm - 0.500mm)
		-	-	φ100mm/H50mm (0.090mm - 0.500mm)
		-	-	φ50mm/H50mm (0.090mm - 0.500mm)

j. Risk Analysis

The PREXION3D was evaluated in accordance with ISO14971:2007. The risk management of the device was deemed satisfactory.

k. Bench Testing

THE YOSHIDA DENTAL MFG. CO., LTD has performed bench tests to ensure safety and effectiveness as follows;

1. Laser safety

   The laser system of the PREXION3D is identical to that of the PANOURA 18S (K111231). Therefore, the test report for IEC 60825-1 for the PANOURA 18S (K111231) is used as the test report for the PREXION3D.

2. Modulation-Transfer Function

   In order to evaluate the spatial resolution of the PreXion3D, we measured the MTF in accordance with IEC 61223-3-5. The spatial resolution of all scan modes met the acceptance criteria.

3. Artifact Analysis

   In order to evaluate the artifact of the image of the PREXION 3D, the images of all scan mode of the PREXION 3D were compared to those of the FineCube (K063622). There was no difference of pattern and strength of the metal artifact between the PREXION 3D and the FineCube(K063622).

The software of the PREXION3D has been validated according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

EMC, Electric safety, and X-ray radiation safety are confirmed in accordance with IEC60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, and IEC 60601-2-32.

l. Conclusion

The PREXION 3D has similar intended use and technical characteristics as the predicate devices including the FINECUBE (k063622) and CS 9300 (k103659). A number of test results and risk analysis indicate that the PREXION 3D meets the requirements of the recognized consensus or voluntary standard. Based on those information, we conclude that the PREXION 3D is substantially equivalent to the predicate devices and does not raise any new questions regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

The Yoshida Dental MFG Co., LTD.
% Dr. Fumiaki Kanai
President and CEO
MIC international
4-1-17 Hongo, Bunkyo-ku
TOKYO, 113-0033, JAPAN

Re: K120948
Trade/Device Name:PREXION 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: Class II
Product Code: OAS
Dated: November, 09, 2012
Received: November 13, 2012

Dear Dr. Kanai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120948

Device Name: PREXION 3D

Indications For Use:

PreXion 3D is intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillo-facial regions at the direction of healthcare professionals as diagnostic support.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
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